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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,798	12/12/2001	Valentin Kramer	31567.3	9144

27683 7590 12/01/2003

HAYNES AND BOONE, LLP
901 MAIN STREET, SUITE 3100
DALLAS, TX 75202

EXAMINER

CHANG, VICTOR S

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/017,798		KRAMER ET AL.	
	Examiner		Art Unit	
	Victor S Chang		1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 IDS
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in response filed 9/2/2003 is acknowledged. The traversal is on the ground(s) that "the applicant is not presently claiming a method of making a different product". Upon reconsideration, the Examiner now agrees that method claims 10-14 mirrors product claims 1-9 with conventional method steps. As such, the restriction requirement of Paper No. 0715 is withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More particularly, in claim 1, lines 3-6, the recitation "wherein one pore size distribution comprises smaller pore sizes than another pore size distribution and the smaller pore size distribution is found within the larger pore size distributions" appear extremely vague, indefinite and confusing. It is unclear to the Examiner how the two pore-size-distributions (or two domains each clearly defines a distinct pore size distribution) differentiate from each other, because any distribution could inherently be arbitrarily further divided into distributions of different sizes.

In claim 9, the phrase "reinforced sheet" is vague and indefinite, it is unclear to the examiner what is the scope of the "reinforced sheet", as it is absent from the Specification. For the purpose of the present Office Action, it is presumed to be any polymer coating which enhances the mechanical properties of the ePTFE sheet.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over admitted prior art.

In the Specification, page 1, lines 14-21, Applicants appear to have admitted that DE 690 03 879 describes an expanded PTFE material comprising a mixture of a PTFE having a high molecular weight of 2,000,000 or more and a PTFE having a low molecular weight of 1,000,000 or less. The size of the pores of the PTFE-material can

be varied by changing the mixing ratio between the high molecular weight PTFE and the low molecular weight PTFE. The PTFE-material can exhibit different shapes, for example a foil, sheet or cube. Further, Applicants also admitted that many similar designs of ePTFE tubes serving as vascular grafts can be found in the market place, and uniaxially expanded ePTFE tube can be reinforced with a ring complex (Specification, page 1, lines 27-33).

For claims 1-5, although the admitted prior art lacks an express teaching of the pore size distribution, it is noted that the scope of the admitted prior art, in particular the use of PTFE molecular weights to vary the pore sizes, are essentially the same as the instantly claimed invention. As such, in the absence of unexpected results, it is believed that suitable pore size distributions are either inherently disclosed, or an obvious optimization to one of ordinary skill in the art. Additionally, in the absence of clearly defined domains, the instantly claimed pore size distributions also appear arbitrary and may be any infinite combinations, as set forth above.

For claims 6-8, Applicants have admitted that it is known art to form different shapes, including sheet and reinforced tube, as set forth above.

For claim 9, it is well known that ePTFE sheet can be coated with a layer of polyurethane polymer to make breathable lining for garment.

Method claims 10-14 essentially mirror the product claims, and employ only conventional method steps, and as such are rejected.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In addition, the following references are cited of interest for making expanded PTFE:

US 4902423 to Bacino is directed to a porous PTFE membrane having a series of rows of nodes running transversely across the membrane.

US 4952630 to Mrogan et al. is directed to a PTFE material comprises aggregations of nodes, short fibrils interconnecting the nodes to form the aggregations and long fibrils interconnecting the aggregations (column 14, lines 45-60).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S Chang whose telephone number is 703-605-4296. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H Morris can be reached on 703-308-2414. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

VSC

DANIEL ZIRKER
PRIMARY EXAMINER
GROUP 1300
1700

Daniel Zinker